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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,069	09/18/2003	Xue-Feng Pei	SYM 112 CON	1434

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KEITH A. JOHNSON
TRANSGENOMIC, INC.
12325 EMMET STREET
OMAHA, NE 68164

EXAMINER	
BERNHARDT, EMILY B	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/667,069	PEI ET AL.	
	Examiner	Art Unit	
	Emily Bernhardt	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-15 and 25-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-15 and 25-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/18/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The abstract of the disclosure is objected to because a structural formula should be set forth showing where the alkylthio must be present . Correction is required. See MPEP ' 608.01(b).

The disclosure is objected to because of the following informalities: Status of parent needs updating in the parent history. Appropriate correction is required.

In the figure present in the disclosure, note the typo appearing in the title, namely "methyl**tho**" .

Claims 10-15, 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1.Recitation of "and...salts" in the main and dependent claims reads on mixtures rather than alternative compounds. "Or…" is suggested.

2.Throughout the claims (se 10,16,17 etc.) halogen is recited followed by a narrower scope of halos in parenthesis which renders the claims unclear as to what is being claimed- all halos or just F,Cl and Br. Clarification is needed.

3.The 3rd choice for R8/R9 in the claims is incomplete as to valency since the "C" in "(CR^{15})" is left with a dangling valence.

4. Scope of method claims 10-12 and 25-27 are indeterminate in scope. Defining a disease(s) by its (their) underlying cause renders the scope of intended uses

indeterminate since the claim language may read on diseases not yet known to be caused by or affected by such action or in ways not yet understood. Additionally, determining whether a given disease responds or not to excessive activation of AMPA receptors involves much experimentation since a negative response from one patient does not mean the drug isnt useful as no drug has 100% effectiveness. Thus what "success rate" determines if a particular inhibitor is effective and how many patients (and dosage regimens) need to be tested? The test for determining compliance with 35 USC 112, par.two is whether applicants have clearly defined "their" invention not what may be discovered by future research as this type of claim language clearly requires.

Claims 10-15,25-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Scope of uses covered by the method claims are not remotely enabled.

These cover entire classes of disorders which include diseases as varied as Alzheimer's, Huntington's Disease, ALS, "functional" disorders of unknown etiology. Such a list which is virtually nonlimiting constitutes "an invitation to experiment" which is not in compliance with 35 USC 112. The references cited in

parent do not remotely evidence that such disorders can be treated simply because a compound possesses antagonistic activity at one or more non-NMDA receptors. In fact the opposite is stated. See concluding remarks in McBurney regarding the lack of "accurate animal models" for studying the feasability of treating chronic neurodegenerative diseases. Also note the following statement found in Ikonomidou (cited by applicants in parent) on p.250 regarding chronic neurodegenerative diseases: "The pharmacology of AMPA antagonists is still not sufficiently known to make predictions about possible success of these drugs in the clinic." . Applicants provide no scientific data in the specification to controvert the findings in the art from which one can reasonably conclude that all of applicants' compounds possess all these uses. Where the assertion of utility is unusual, difficult to treat or speculative, the examiner has authority to require evidence that tests relied on are reasonably predictive of in vivo efficacy by those skilled in the art. See for example, In re Ruskin 148 USPQ 221; Ex parte Jovanovics 211 USPQ 907. Note MPEP. 2164.05(a). Note also the criteria for enablement as set out in In re Wands cited in MPEP 2164.01(a),August 2000 edition. Thus given the level of skill in this art which is low and the lack of direction (i.e. art-recognized tests) as well as working examples employing such tests, this rejection is being applied.

Also see Le Peilet, and Lipton,cited in parent, directed to nonNMDA antagonists having gone more testing than herein. These references at best strongly suggest the 3 uses described in the specification on p.2, lines 13-15 are enabled. Limiting to said uses would not be objected to.

Applicants' IDS has been considered except for March which has no pages indicated for review on the 1449 and only title page was provided in parent file.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is (571) 272-0664.

If attempts to reach the examiner by phone are unsuccessful, the supervisor for AU 1624, Dr. Mukund Shah, can be reached at (571)272-0674.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

E Bernhardt

EMILY BERNHARDT

PRIMARY EXAMINER

Group 1600